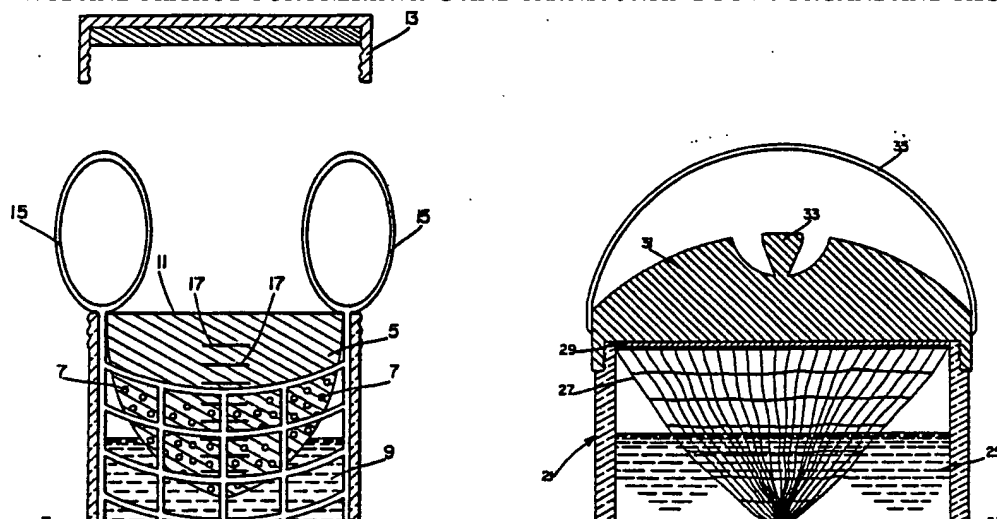




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A01N 1/02	A1	(11) International Publication Number: WO 91/03934 (43) International Publication Date: 4 April 1991 (04.04.91)
<p>(21) International Application Number: PCT/US90/04895</p> <p>(22) International Filing Date: 31 August 1990 (31.08.90)</p> <p>(30) Priority data: 407,480 14 September 1989 (14.09.89) US</p> <p>(71)(72) Applicant and Inventor: KRASNER, Paul, R. [US/US]; 285 Maugers Mill Road, Pottstown, PA 19464 (US).</p> <p>(74) Agent: EILBERG, William, H.; 820 Homestead Road, Jen- kintown, PA 19046 (US).</p> <p>(81) Designated States: AT (European patent), AU, BB, BE (Eu- ropean patent), BF (OAPI patent), BG, BJ (OAPI pa- tent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CM (OAPI patent), DE (Euro- pean patent)*, DK (European patent), ES (European pa- tent), FI, FR (European patent), GA (OAPI patent), GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent),</p>		<p>MW, NL (European patent), NO, RO, SD, SE (European pa- tent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
(54) Title: APPARATUS AND METHOD FOR PRESERVING AND TRANSPORTING BODY ORGANS AND TISSUES		
		
<p>(57) Abstract</p> <p>Body organs, or severed limbs or digits, are stored and transported in a cartridge (21) which is inserted into, and removable from a refrigeration unit. The cartridge (21) includes an insulated container (23), and a net (27) suspended within the container. The container also has a heat-induced foil seal (29), a lid (31), and a handle (33), and is filled with a solution (25) which preserves body tissues. The interior of the refrigeration unit is shaped to receive the cartridge (21), and the refrigeration unit has a closable top for completely enclosing the cartridge within the unit. One such refrigeration unit is provided in an ambulance, and another substantially identical refrigeration unit is kept in a hospital. A severed limb or a body organ is placed within the cartridge (21), which is inserted into the refrigeration unit in the ambulance. The invention also includes an apparatus and method for storing and preserving bone graft material. The material is dropped onto a flexible, clear diaphragm (5), the diaphragm being suspended from a removable basket (3), the basket being inserted into a container (1) filled with a preservative solution (9). Calibration marks (17) on the diaphragm (5) show the amount of bone graft material remaining within the container (1).</p>		

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APPARATUS AND METHOD FOR PRESERVING AND TRANSPORTING
BODY ORGANS AND TISSUES

BACKGROUND OF THE INVENTION

This invention relates to the field of preservation and storage of body parts and tissues. The invention includes a method and apparatus for storing and preserving tissues such as bone graft material. The invention also includes a method of preserving and storing amputated or severed limbs, or body organs for transplantation.

U.S. Patent Nos. 4,689,014 and 4,802,853 disclose a method and apparatus for preserving and reimplanting a tooth which has been suddenly knocked out of its socket. The latter patents show a container filled with a tooth-preserving solution, and a basket having a net inserted into the container. The tooth is held within the net, and is immersed in the solution. The tooth is transported while sitting in the net within the container. When dental assistance is available, the container is opened, the tooth is removed from the net, and the tooth is reimplanted. The disclosures of the above-cited U.S. patents are incorporated by reference herein.

The devices shown in the above-cited patents are most suitable for use in preserving and transporting exarticulated teeth. But there is also a need for preserving and transporting other body parts and tissues, such as bone graft material, and amputated, severed, or transplanted body parts or organs. The present invention therefore provides a method and apparatus for handling body tissues, such as bone graft material. The invention also includes a method of transporting and/or storing amputated or severed digits or body organs. This method can be used in emergency

situations, and can also be used in the routine transportation and storage of organs for transplantation. The method of the present invention therefore enhances the ability of physicians to reattach limbs which have been accidentally and suddenly severed, and also improves the efficiency with which body organs can be transplanted.

SUMMARY OF THE INVENTION

The invention includes an apparatus and method for preserving and/or transporting body tissues, such as bone graft material. The apparatus includes a container having a removable basket disposed therein, the basket being attached to a flexible diaphragm. The diaphragm, preferably formed of a clear plastic, has a plurality of pin holes. The container is filled with a solution capable of preserving the bone graft material. The basket is attached to one or more handles. With these handles, the basket can be easily lifted out of the container. The diaphragm can have a plurality of calibration marks to indicate the amount of bone graft material remaining. The container is sealed with a foil, and has a removable lid.

In using the apparatus described above, the container lid is removed, and the foil is torn off. The bone graft material is dropped into the diaphragm, and the lid is replaced. The material becomes totally immersed within the preserving solution. When the graft material is needed, the basket handles are lifted, and the basket is removed from the container. Due to the pin holes, the solution drains from the diaphragm. The basket can then be placed on a table and the bone graft material can be removed as needed. Depending on the quantity of material remaining in

INTERNATIONAL SEARCH REPORT

International Application No **PCT/US90/04895**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³ According to International Patent Classification (IPC) or to both National Classification and IPC IPC(5): A01N 1/02 USS. Cl: 435/1		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
U.S	435/1	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁴		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US,A, 4,689,014 (Krasner) 25 August 1987 See entire document..	1-7
Y	US,A, 3,777,507 (Burton et al.) 11 December 1973 See entire document.	8-20
Y	US,A, 3,545,221 (Swenson et al.) 08 December 1970. See entire document.	8-20
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ¹ 06 November 1990	Date of Mailing of this International Search Report ² <div style="font-size: 1.5em; font-weight: bold;">22 JAN 1991</div>	
International Searching Authority ¹ ISA/US	Signature of Authorized Officer ²⁰ <div style="font-family: cursive; font-size: 1.2em;">Sam Rosen</div> Sam Rosen	

Description

APPARATUS AND METHOD FOR PRESERVING AND TRANSPORTING BODY ORGANS AND TISSUES BACKGROUND OF THE INVENTION

This invention relates to the field of preservation and storage of body parts and tissues. The invention includes a method and apparatus for storing and preserving tissues such as bone graft material. The invention also includes a method of preserving and storing amputated or severed limbs, or body organs for transplantation.

U.S. Patent Nos. 4,689,014 and 4,802,853 disclose a method and apparatus for preserving and reimplanting a tooth which has been suddenly knocked out of its socket. The latter patents show a container filled with a tooth-preserving solution, and a basket having a net inserted into the container. The tooth is held within the net, and is immersed in the solution. The tooth is transported while sitting in the net within the container. When dental assistance is available, the container is opened, the tooth is removed from the net, and the tooth is reimplanted. The disclosures of the above-cited U.S. patents are incorporated by reference herein.

The devices shown in the above-cited patents are most suitable for use in preserving and transporting exarticulated teeth. But there is also a need for preserving and transporting other body parts and tissues, such as bone graft material, and amputated, severed, or transplanted body parts or organs. The present invention therefore provides a method and apparatus for handling body tissues, such as bone graft material. The invention also includes a method of transporting and/or storing amputated or severed digits or body organs. This method can be used in emergency situations, and can also be used in the routine transportation and storage of organs for transplantation. The method of the present invention therefore enhances the ability of physicians to reattach limbs which have been accidentally and suddenly severed, and also improves the efficiency with which body organs can be transplanted.

SUMMARY OF THE INVENTION

The invention includes an apparatus and method for preserving and/or transporting body tissues, such as bone graft material. The apparatus includes a container having a removable basket disposed therein, the basket being attached to a flexible diaphragm. The diaphragm, preferably formed of a clear plastic, has a plurality of pin holes. The container is filled with a solution capable of preserving the bone graft material.

The basket is attached to one or more handles. With these handles, the basket can be easily lifted out of the container. The diaphragm can have a plurality of calibration marks to indicate the amount of bone graft material remaining. The container is sealed with a foil, and has a removable lid.

In using the apparatus described above, the container lid is removed, and the foil is torn off. The bone graft material is dropped into the diaphragm, and the lid is replaced. The material becomes totally immersed within the preserving solution. When the graft material is needed, the basket handles are lifted, and the basket is removed from the container. Due to the pin holes, the solution drains from the diaphragm.

The basket can then be placed on a table and the bone graft material can be removed as needed. Depending on the quantity of material remaining in the diaphragm, as indicated by the calibration marks, additional material can be added periodically to the diaphragm.

The invention also includes a method of transporting and storing an amputated or severed body part, or an organ to be transplanted. This method includes the use of a removable cartridge for storing the organ or body part. The cartridge is an insulated container, filled with a solution capable of preserving the organ or body part, and having a net suspended within the container. The container also has a foil seal, a lid, and a handle. The cartridge is inserted into a refrigeration unit, the interior of which is shaped to receive the cartridge.

In one aspect of the method of the invention, a refrigeration unit is placed in an ambulance, or other vehicle, and another identical unit is located in a hospital. The ambulance also carries a cartridge, of the type described above. The ambulance is driven to the site of an accident, and a severed body part is inserted into the cartridge. The cartridge is closed and the ambulance is driven to the hospital. The cartridge is lifted out of the mobile refrigeration unit of the ambulance, and inserted into the stationary refrigeration unit at the hospital. A new cartridge is placed in the ambulance for use in the next emergency.

In another aspect of the method, the removable cartridge is used to store and/or transport an organ for transplantation. The cartridge can be inserted into a refrigeration unit which has its own source of power for refrigeration, so that the unit can be shipped in a vehicle, without requiring an external source of power. The organ can therefore be stored, temporarily, at a first location, near the donor, then transported to a

second location, near the recipient, and stored until it is to be transplanted. The cartridge containing the organ can thus be stored within three substantially similar, but distinct, refrigeration units of the types described above.

It is therefore an object of the present invention to provide an apparatus and method for storing and/or transporting body tissues, such as bone graft material and the like.

It is another object to provide a method of storing and/or transporting severed limbs or body parts which are intended to be reattached.

It is another object to increase the speed and efficiency with which a severed body part can be transported to a hospital for prompt reattachment.

It is another object to improve the efficiency with which the medical profession can react to emergencies involving severed limbs.

It is another object to provide a method which facilitates the transportation of organs for transplantation.

It is another object to provide a method of storage and transportation of body organs, wherein an organ is transported in a single cartridge, the cartridge being insertable into a plurality of similar refrigeration units positioned at various locations.

Other objects and advantages of the invention will be apparent to those skilled in the art, from a reading of the following brief description of the drawings, the detailed description of the invention, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a diagram of an apparatus for storing and preserving body tissues, such as bone graft material.

Figure 2 is a diagram of a cartridge for preserving a severed body part or an organ to be transplanted, the cartridge being intended for insertion into a refrigeration unit.

Figure 3 is a diagram of a refrigeration unit, adapted for receiving the cartridge of Figure 2, and intended for use in an ambulance or hospital.

Figure 4 is a diagram showing a refrigeration unit similar to that of Figure 3, except that this unit does not require an external source of power.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 is a diagram of an apparatus for storing and preserving body tissues, such as bone graft material, or the like. The apparatus includes container 1, within which is located removable basket 3. The basket can be of similar construction to that shown in the above-cited patents, but many variations are possible, within the scope of the invention, provided that the basket is constructed to allow liquid to flow through it.

Attached to the basket is diaphragm 5 having a plurality of pin holes 7. The diaphragm is preferably attached to the basket near its upper end, as shown in Figure 1. The container is filled with preserving fluid 9. This fluid can be one of the solutions described in the abovesited patent, or it can be another solution, such as that sold under the trademark Viaspan, by E. I. DuPont de Nemours & Co. The fluid can also be any other solution capable of preserving body tissues. The invention should not be deemed limited to the use of a particular solution.

The container is sealed with a foil layer 11 and has a lid 13. The lid is shown removed from the container, in Figure 1, for the sake of clarity. As shown in the figure, the lid is designed to screw onto the container. The foil layer is preferably heat-sealed to the container, so that the solution can be stored for a relatively long period, without losing effectiveness, within the container, while the apparatus is awaiting use. Handles 15 are attached to the basket, at about the same point at which the diaphragm is attached. The handles may be folded down, over the rim of the basket, in the same manner shown in the above-cited patents. In the preferred embodiment, the diaphragm is a clear plastic, and has calibration marks 17, to indicate the amount of material remaining within the diaphragm.

The apparatus of Figure 1 is used in the following manner. The apparatus is initially sealed with the foil and closed with the lid, with the preserving solution located inside. As stated above, the apparatus is stored in this form for an indefinite period, the period being limited only by the shelf life of the preserving solution.

When it is desired to use the apparatus, the lid is first removed, and the foil seal is broken. The tissue to be preserved, such as bone graft material, is dropped into the container, and comes to rest on the diaphragm. The container holds a sufficient quantity of solution such that the material is totally immersed. The container lid is replaced, and the apparatus is stored. When the preserved material is needed, the lid is

removed, and the handles are grasped so as to remove the basket slowly from the container. As the basket is removed from the container, residual solution flows out of the pin holes and into the container, leaving only the bone graft material, or other material, in the diaphragm.

The basket is then placed on a table, and the preserved material is removed as needed. Additional material can also be added to the diaphragm. The calibration marks indicate the quantity of material remaining. The calibration marks are preferred, but not absolutely necessary.

Figures 2-4 illustrate another embodiment of the invention, which is a method for storing and/or transporting a severed body part, or an organ for transplantation. Unless otherwise indicated, the term "organ" is used to include both an organ for transplantation and a severed or amputated limb.

Figure 2 shows a cartridge in which an organ (not shown) can be stored according to the method of the present invention. Cartridge 21 includes a container having insulated walls 23. Preferably, walls 23 are made of a plastic which enables the device to maintain a cool temperature inside the container. The container is filled with a preserving solution 25. This solution can be the same as discussed above, or any other solution capable of preserving body organs or parts. Again, the choice of solution is not part of this invention, and any suitable preserving solution can be used.

Net 27 is attached to the wall of the container, as shown. The net should be of sufficient strength to hold the organ. A sufficient quantity of solution is present such that an organ dropped into the net will be totally immersed. The interior of the cartridge is sealed by foil layer 29, and the cartridge is closed with a lid 31. Lid 31 has a handle 33, and the lid preferably is screwed onto the wall of the cartridge, as shown. Other means of attachment can be used. Also attached to the cartridge wall is a cartridge handle 35. This handle folds over, such that the cartridge will fit within the refrigeration unit to be described.

Figure 3 shows a refrigeration unit 41 that can be placed in an ambulance, or other vehicle, and also in a hospital, such as in an emergency room or operating room. Figure 3 also shows the cartridge inserted into the unit. Refrigeration unit 41 includes walls 43 within which are located refrigeration coils 45, and compressor motor 47. An automatic on-off switch 49 is actuated by thermostat 51. Switch 49, as controlled by the thermostat, turns the compressor motor on and off, so as to maintain the temperature of the cartridge at a desired level. The compressor motor is powered by an external power source, as indicated by plug 53.

If the unit is in an ambulance, the power source is generally the DC available within the vehicle; if the unit is in a hospital, the power source can be from an ordinary AC line. It is assumed that the refrigeration unit includes suitable means for converting a DC voltage to AC, as needed.

The compressor motor can also be controlled manually, by rheostat 52. Rheostat 52 is controlled by a knob (not shown), or its equivalent, located on the exterior of the refrigeration unit. The rheostat can be used to change the temperature setting as desired. The rheostat can also include an on-off control. In transplanting a chilled organ, it is known to be desirable to heat the organ gradually before performing the transplantation operation. The rheostat makes it easy to accomplish this gradual heating.

The refrigeration unit also has a top 55, the top having handle 57.

The top may be in two portions, as shown in Figure 3, or it can be formed in one portion. The top rotates in the direction indicated by the arrow.

A holding sponge 59 may be affixed to each portion of the top. Note that when cartridge 21 is inserted within the refrigeration unit, its handle 35 (shown in Figure 2) has been folded over, so that the top 55 can be closed over the cartridge, thereby forming a fully-enclosed region within the refrigeration unit.

Figure 4 is similar to Figure 3, and shows another refrigeration unit, with a cartridge inserted. The reference numerals common to these figures indicate identical components. The only difference between Figures 3 and 4 is that Figure 4 includes battery pack 61, which serves as an alternative source of power for the refrigeration unit. The battery pack is used when the refrigeration unit is being transported on an airplane or other vehicle, and where an external source of power is not available. The batteries are preferably rechargeable, so that they can be recharged when the unit is again connected to an external source of power. Regardless of the type of power used, the refrigeration unit should be capable of cooling its contents to about 32° F.

The apparatus of Figures 2-4 can be used in several ways. One method of use is in emergency situations, wherein limbs or extremities have been accidentally severed. In this case, the procedure is as follows.

An ambulance, or other vehicle, is equipped with a refrigeration unit, of the type shown in Figure 3. The ambulance also has a cartridge, as shown in Figure 2. The cartridge is stored within the refrigeration unit, and is kept at the constant temperature of about 20 C. Preferably, the cartridge is new, i.e. its seal has not

been broken. Another refrigeration unit, substantially identical to that located in the ambulance, is stationed at a hospital, preferably at or near an operating room.

The ambulance is driven to the site of the accident, and the severed limb is brought to the ambulance. The refrigeration unit is opened, and the cartridge lid is unscrewed. The foil seal is then broken, exposing the net which is immersed in the preserving solution. The severed limb or digit is dropped into the solution, and comes to rest in the net. The limb or digit becomes immersed within the solution. The cartridge lid is screwed into the cartridge wall. The top of the refrigeration unit is replaced, and the ambulance is driven to the hospital, with the patient and the cartridge.

At the hospital, the refrigeration unit is opened, and the cartridge is removed by its handle (35), and carried to the refrigeration unit in the hospital. There, the cartridge is kept cool until physicians are ready to perform the reattachment. Meanwhile, a new cartridge is placed in the ambulance, to be ready for the next emergency. When the limb is to be reattached, the cartridge is removed from the refrigeration unit at the hospital, the limb is retrieved, and the operation is performed.

The above-described method can be varied. It is possible to remove the cartridge from the refrigeration unit, when the ambulance arrives at the site of an accident, and to carry the cartridge, by its handle, to the vicinity of the victim. After the severed limb is placed within the cartridge, the cartridge is then inserted into the refrigeration unit and driven to the hospital as described above.

Another method of using the apparatus shown in Figure 2-4 is in transporting organs for transplantation. In this method, an organ removed from a donor is placed in a cartridge, of the type shown in Figure 2. Preferably the cartridge is new, so placing the organ in the cartridge requires opening the cartridge lid and breaking the foil seal.

After the organ is dropped into the net, the cartridge lid is replaced.

Preferably, replacement of the lid is done by screwing the lid into the cartridge wall. The cartridge may initially be located within a refrigeration unit. If the cartridge is initially located outside of such unit, it is immediately transferred to such a refrigeration unit, either shortly before or shortly after the organ is inserted. The top of the refrigeration unit is closed, and the organ is kept cool, within the cartridge, in the hospital.

When the organ is to be transported, the top of the refrigeration unit is opened, and the cartridge is lifted out by its handle. The cartridge is then inserted into a mobile refrigeration unit, of the type shown in Figure 4, and the top of the mobile unit is closed. The mobile refrigeration unit is then transported to the desired location. If the mobile unit is not located near an external source of power, such as while being transported by plane, or by another vehicle, its battery pack insures that the organ is kept cool.

Note that the mobile refrigeration unit may be transported by an ambulance, or it may be carried within some other vehicle, such as a truck, an airplane, or any other means of transportation. If no source of power, for the refrigeration unit, is available within the vehicle, then the battery pack is used.

At the final destination, the mobile refrigeration unit is opened, and the cartridge removed. The cartridge is then inserted into a stationary refrigeration unit, and the organ is then kept chilled until it is to be transplanted.

While the invention has been described with respect to the embodiments illustrated, it is understood that many variations are possible.

The structure of the cartridge can be varied: the means of attachment of the lid, the construction of the net, and the shape of the handles are all items which can be modified. The apparatus and method for storing body tissues is not limited to use with bone, graft material, but can be used to store other tissues. The invention is also not limited to the use of an ambulance; other vehicles can be used. The above-described modifications of the invention, and others which will be apparent to those skilled in the art, should be deemed within the spirit and scope of the following claims.

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Claims

What is claimed is:

1. Apparatus for preserving bone graft material, comprising:
 - a) a container filled with a solution capable of preserving bone graft material,
 - b) a basket, disposed within the container, the basket being removable from the container, the basket being attached to at least one handle means, and
 - c) a diaphragm connected to the basket and disposed within the basket, the diaphragm being capable of holding a quantity of bone graft material, the diaphragm having a plurality of holes.
2. The apparatus of Claim 1, wherein the diaphragm is made of a generally clear material, the diaphragm having a set of marks for indicating the quantity of bone graft material within the diaphragm.
3. The apparatus of Claim 2, wherein the diaphragm is made of a clear plastic.
4. The apparatus of Claim 1, wherein the container has a lid.
5. Apparatus for preserving bone graft material, comprising:
 - a) a container filled with a solution capable of preserving bone graft material, the container having a lid,
 - b) a basket, disposed within the container, the basket being freely removable from the container, the basket being attached to a pair of handles, such that the basket can be lifted out of the container, by pulling on the handles, and
 - c) a diaphragm connected to the basket and disposed within the basket, the diaphragm being made of a clear plastic material capable of holding a quantity of bone graft material, the diaphragm having a plurality of holes, the diaphragm also having a set of calibration marks for indicating the quantity of bone graft material within the diaphragm.
6. A method of preserving bone graft material, comprising the steps of:
 - a) removing a lid from a container, the container being filled with a solution capable of preserving bone graft material, the container having a basket, the basket being disposed within the container and being attached to at least one handle, the basket also being attached to a diaphragm, the diaphragm having a plurality of holes,
 - b) dropping the bone graft material into the diaphragm, the diaphragm having been inserted to a sufficient depth such that the solution covers the bone graft material,
 - c) lifting the basket by grasping the handles, such that the basket is removed from the container, and such that the solution within the diaphragm escapes through the holes into the container, and
 - d) removing the basket from the container and removing the bone graft material from the diaphragm.
7. The method of Claim 6, wherein the diaphragm has a plurality of calibration marks, wherein the diaphragm is generally clear, and wherein the method further comprises the step of observing the quantity of bone graft material remaining in the diaphragm, adding more bone graft material to the diaphragm, and storing the diaphragm, with the bone graft material, within the container filled with the solution.
8. A method of preserving and transporting a body organ or amputated extremity, comprising the steps of:
 - a) equipping an ambulance with a first refrigeration unit and a removable cartridge, the cartridge being disposed within the first refrigeration unit, the cartridge having insulating walls and a net attached to the walls, the cartridge also having a seal, the cartridge having a lid affixed thereto, over the seal, the cartridge having a handle, the cartridge being filled with a solution capable of preserving a body organ, the first refrigeration unit comprising an insulated enclosure shaped to receive the cartridge, the first refrigeration unit having a closable top,
 - b) placing a second refrigeration unit substantially identical to that described in step (a) in a hospital operating room,
 - c) driving the ambulance to the site of the body organ,
 - d) opening the top of the first refrigeration unit,
 - e) removing the lid of the cartridge, and breaking the seal of the cartridge,
 - f) dropping the body organ into the net, such that the organ is immersed in the solution,
 - g) replacing the lid of the cartridge,
 - h) driving the ambulance to the hospital,
 - i) removing the cartridge from the first refrigeration unit by grasping its handle, and transferring the cartridge to the second refrigeration unit, in the hospital operating room, such that the cartridge remains refrigerated, and
 - j) removing the cartridge from the second refrigeration unit when it is desired to implant the organ into a patient.

9. The method of Claim 8, further comprising the step of placing a second cartridge into the first refrigeration unit, the second cartridge being substantially identical to the first.
10. The method of Claim 8, further comprising the steps of adjusting the temperature of the cartridge by adjusting a temperature control on the first and second refrigeration units.
11. The method of Claim 10, wherein the adjusting steps are performed by setting a thermostat to a desired temperature.
12. The method of Claim 10, wherein the adjusting steps are performed by setting a rheostat to a desired temperature.
13. A method of preserving and transporting a body organ or amputated extremity, comprising the steps of:
- a) equipping an ambulance with a first refrigeration unit and a removable cartridge, the cartridge being disposed within the first refrigeration unit, the cartridge having walls and a net attached to the walls, the cartridge being filled with a solution capable of preserving a body organ, the first refrigeration unit comprising an enclosure shaped to receive the cartridge,
 - b) placing a second refrigeration unit substantially identical to that described in step (a) in a hospital,
 - c) driving the ambulance to the site of the body organ,
 - d) dropping the body organ into the cartridge, such that the organ rests within the net, and such that the organ is immersed in the solution,
 - e) driving the ambulance to the hospital, and
 - f) transferring the cartridge from the first refrigeration unit to the second refrigeration unit.
14. A method of storing and transporting a body organ for transplantation, the method comprising the steps of:
- a) inserting the organ, received from a donor, into a removable cartridge, the cartridge being located within a first refrigeration unit, the cartridge having insulating walls and a net attached to the walls, the cartridge also having a seal, the insertion step including the step of breaking the seal, the cartridge having a lid affixed thereto, over the seal, the cartridge having a handle, the cartridge being filled with a solution capable of preserving a body organ, the refrigeration unit comprising an insulated enclosure shaped to receive the cartridge, the refrigeration unit having a closable top,
 - b) storing the organ in the first refrigeration unit,
 - c) removing the cartridge from the first refrigeration unit by opening the top of the first refrigeration unit and lifting the cartridge by its handle, and placing the cartridge into a second refrigeration unit, the second refrigeration unit being substantially identical to the first, except that the second refrigeration unit has an independent source of power for maintaining its interior at a desired temperature,
 - d) transporting the second refrigeration unit to another location,
 - e) removing the cartridge from the second refrigeration unit and inserting the cartridge into a third refrigeration unit, the third refrigeration unit being substantially identical to the first refrigeration unit, and
 - f) storing the cartridge in the third refrigeration unit until the organ is ready for implantation.
15. The method of Claim 14, wherein step (d) includes the step of activating said independent power source for the second refrigeration unit, the transporting step being performed without electrically connecting the second refrigeration unit to any external component.
16. The method of Claim 14, further comprising the steps of adjusting the temperature of the cartridge by adjusting a temperature control on the first, second, and third refrigeration units.
17. The method of Claim 14, wherein the adjusting steps are performed by setting a thermostat to a desired temperature.
18. The method of Claim 14, wherein the adjusting steps are performed by setting a rheostat to a desired temperature.
19. A method of storing and transporting a body organ for transplantation, the method comprising the steps of:
- a) inserting the organ, received from a donor, into a removable cartridge, the cartridge being located within a first refrigeration unit, the cartridge having walls and a net attached to the walls, the cartridge being filled with a solution capable of preserving a body organ, the refrigeration unit comprising an enclosure shaped to receive the cartridge,
 - b) storing the organ in the first refrigeration unit,
 - c) removing the cartridge from the first refrigeration unit and placing the cartridge into a second refrigeration unit, the second refrigeration unit being substantially identical to the first, except that the second refrigeration unit has an independent source of power for maintaining its interior at a desired temperature,

- d) transporting the second refrigeration unit to another location,
- e) removing the cartridge from the second refrigeration unit and inserting the cartridge into a third refrigeration unit, the third refrigeration unit being substantially identical to the first refrigeration unit, and
- f) storing the cartridge in the third refrigeration unit until the organ is ready for implantation.

20. The method of Claim 19, wherein step (d) includes the step of activating said independent power source for the second refrigeration unit, the transporting step being performed without electrically connecting the second refrigeration unit to any external component.

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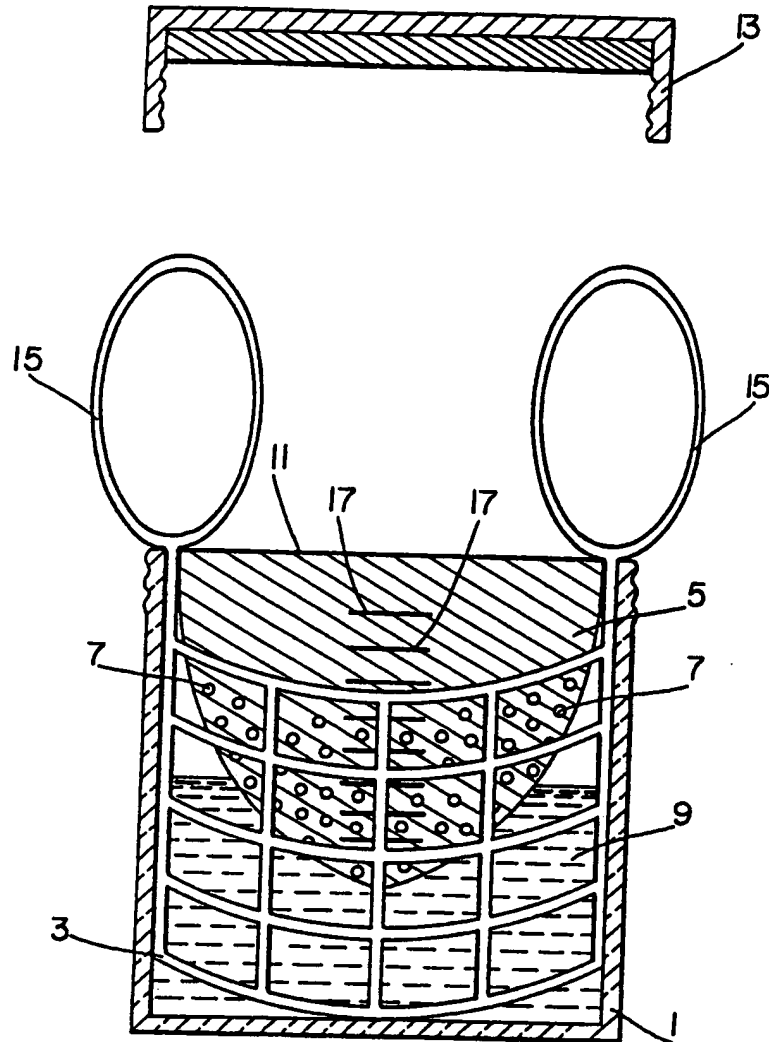


FIG. 1

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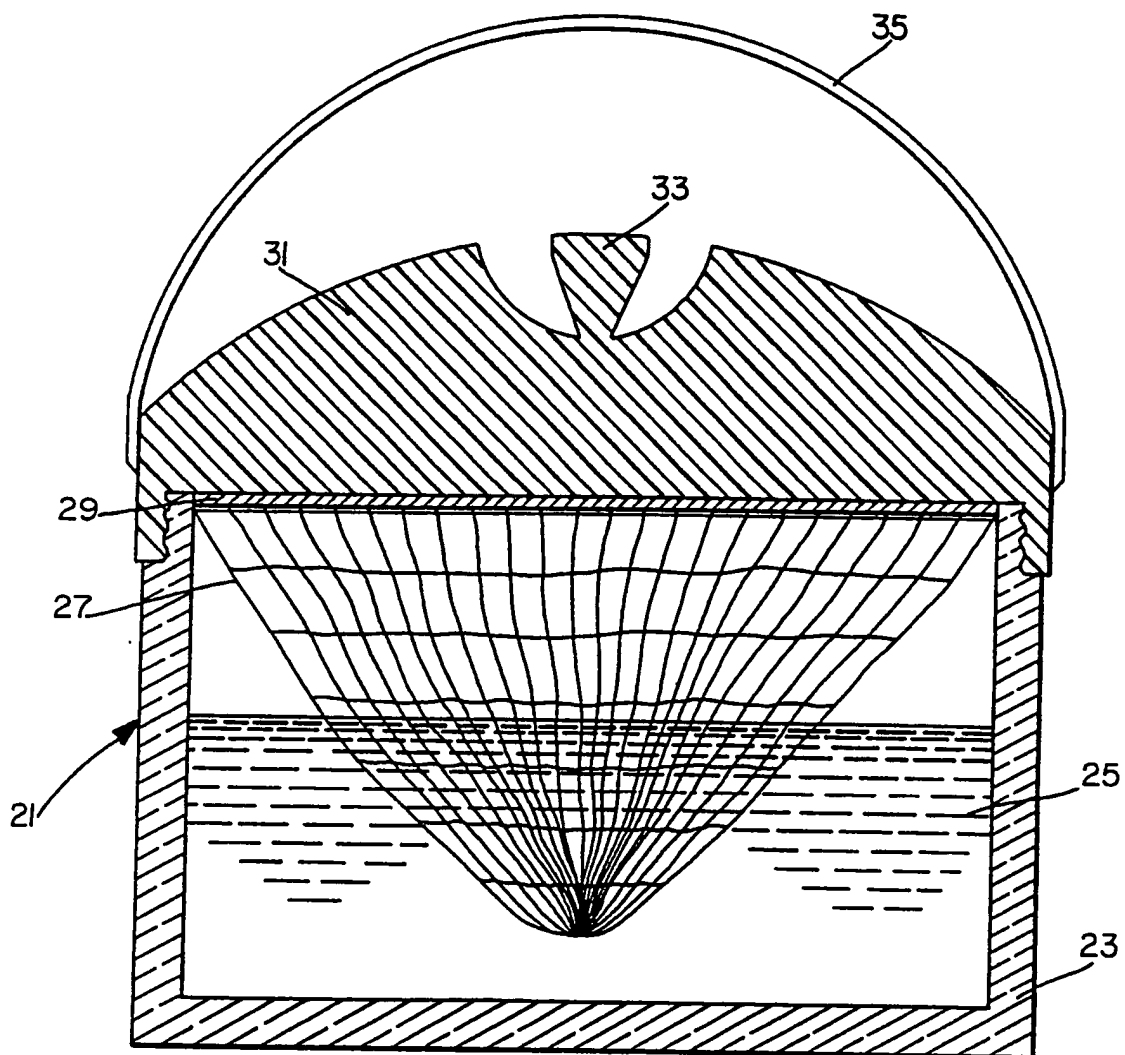


FIG. 2

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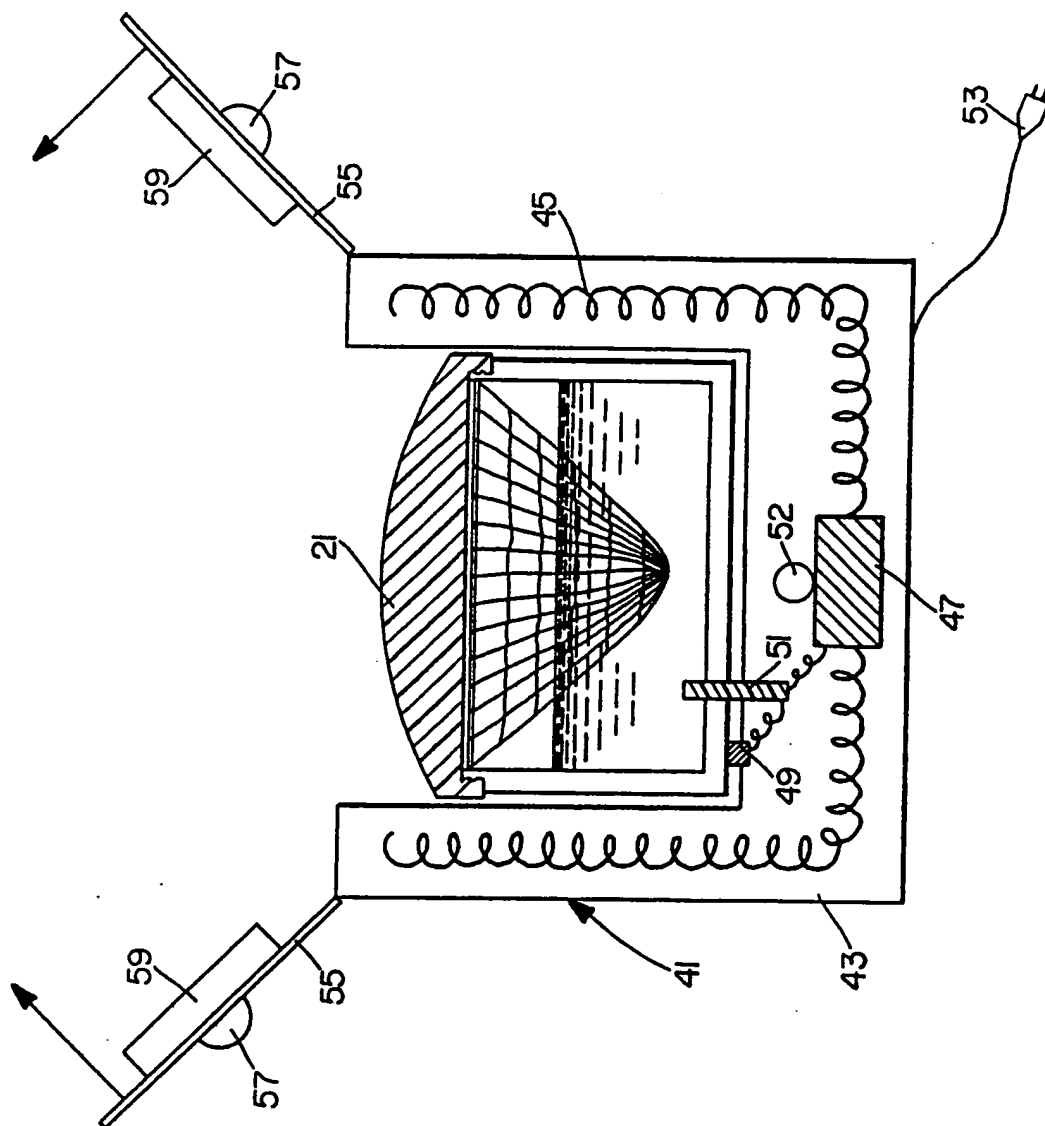


FIG. 3

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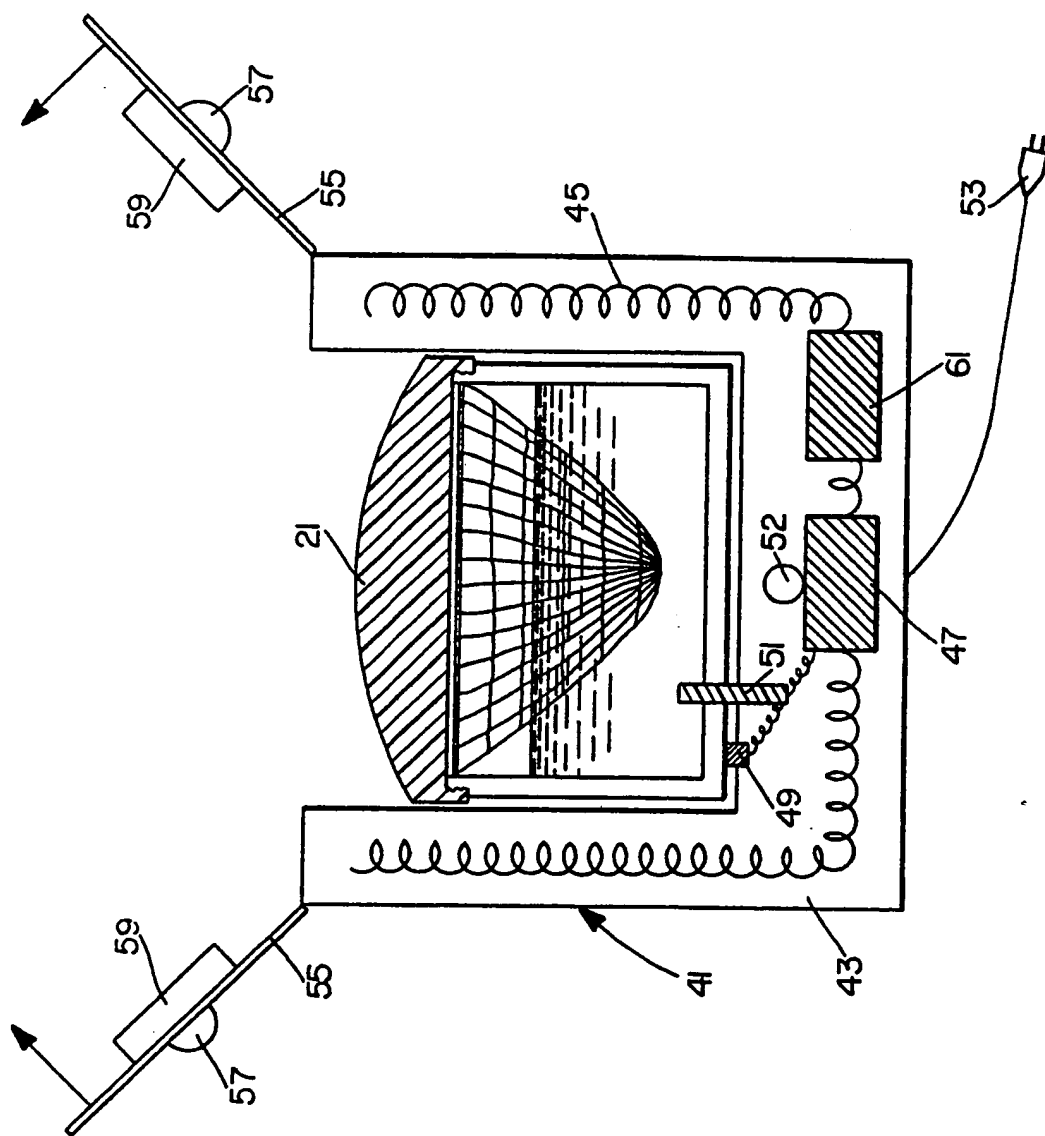


FIG. 4